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09/029,830	03/10/1998	PEET KASK	P61813USO	6621

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[REDACTED] EXAMINER

BAKER, MAURIE GARCIA

ART UNIT	PAPER NUMBER
1639	26

DATE MAILED: 03/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. <b>09/029,830</b>	Applicant(s) <b>Kask</b>
Examiner <b>Maurie G. Baker</b>	Art Unit <b>1639</b>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on Dec 26, 2002

2a)  This action is FINAL.      2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 29-76 is/are pending in the application.

4a) Of the above, claim(s) 45-48, 58, 59, 65, and 74-76 is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 29-44, 49-57, 60-64, and 66-73 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.

2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

1)  Notice of References Cited (PTO-892)

4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

5)  Notice of Informal Patent Application (PTO-152)

3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

6)  Other: \_\_\_\_\_

## **DETAILED ACTION**

1. Applicant's Response filed December 26, 2002 (Paper No. 25) is acknowledged. No were amended, added or cancelled. Therefore, claims 29-76 are currently pending.

### *Election/Restriction*

2. Applicant's election of species is noted. Because applicant did not distinctly and specifically point out the supposed errors in the election of species requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
3. Therefore, claims 45-48, 58, 59, 65 and 74-76 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected species, there being no allowable generic or linking claim.
4. Claims 29-44, 49-57, 60-64 and 66-73 are examined on the merits in this action.

### *Claim Rejections - 35 USC § 112*

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
6. Claims 29-44, 49-57, 60-64 and 66-73 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in

such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

To satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. Applicant's claims are directed to a "method for characterizing a sample" by "determining a distribution function of the number of photon counts" and "determining a distribution function of specific brightness of the particles based on the distribution function of the number of photon counts measured, by finding out the model of the sample yielding the closest fit between the experimentally determined and an expected distribution function of the number of photon counts, wherein the expected distribution function of the number of photon counts is calculated using the characteristics of a spatial brightness function". The claims use generic terminology such as "determining", "distribution function of the number of photon counts", and "characteristics of a spatial brightness function". These terms are set forth in the instant disclosure but are not adequately described.

The instant specification discloses no specific examples whatsoever of carrying out these method steps. It is unclear whether the claimed method was even employed in the Examples listed in the specification as none of the modeling, determining of functions (either experimental or "expected") or "characteristics of a spatial brightness function" are particularly set forth. The

method steps are set forth in generic language in the claims and no details on how they are to be carried out are set forth in the instant specification. The use of the above terminology without any description and/or exemplification of how the claimed process is to be carried out constitutes a written description problem in the instant case as it is completely unclear that applicant was in possession of the claimed genus of method.

Adequate disclosure, like enablement, requires *representative examples* which provide reasonable assurance to one skilled in the art that *applicant had possession of the full scope of the claimed invention*. The more unpredictable the art the greater the showing required (e.g. by “representative examples”) for both enablement and adequate disclosure. The language of the specification should describe the claimed invention so that one skilled in the art can recognize what is claimed. The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. *University of California v. Eli Lilly and Co.* (U.S. Court of Appeals Federal Circuit (CAFC) 43 USPQ2d 1398 7/22/1997 Decided July 22, 1997; No. 96-1175).

Therefore it is deemed that the disclosure is neither representative of the claimed genus, nor does it represent a substantial portion of the claimed genus. Thus, there is not adequate support in the instant specification for the claimed invention.

7. Claims 29-44, 49-57, 60-64 and 66-73 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors can include, but are not limited to:

- (1) the breadth of the claims;
- (2) the nature of the invention;
- (3) the state of the prior art;
- (4) the level of one of ordinary skill;
- (5) the level of predictability in the art;
- (6) the amount of direction provided by the inventor;
- (7) the existence of working examples; and
- (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

(1-2) The breadth of the claims and the nature of the invention: The claims are drawn to "method for characterizing a sample" by "determining a distribution function of the number of photon counts" and "determining a distribution function of specific brightness of the particles based on the distribution function of the number of photon counts measured, by finding out the model of the sample yielding the closest fit between the experimentally determined and an expected distribution function of the number of photon counts, wherein the expected distribution function of the number of photon counts is calculated using the characteristics of a spatial brightness function". No specifics

on the actual functions, models or determinations to be used are set forth. This represents broad scope.

(3 and 5) The state of the prior art and the level of predictability in the art:

Various methods for modeling and determination of a distribution function of photon counts were known in the art at the time of filing; however, the selection of such methods for various samples was not at all predictable. The specification gives no guidance to permit one of skill in the art to determine how to carry out the claimed methodology and the possible variants are sufficiently diverse that one of ordinary skill would not be able to predict which methodology to be used.

Applicant's claimed scope of compounds represents only an invitation to experiment to determine the "distribution function of the number of photon counts", "distribution function of specific brightness of the particles", "model of the sample yielding the closest fit", "expected distribution function" and "characteristics of a spatial brightness function".

(4) The level of one of ordinary skill: The level of skill would be high, most likely at the Ph.D. level. Such persons of ordinary skill in this art, given its unpredictability, would have to engage in undue (non-routine) experimentation to carry out the invention as claimed.

(6-7) The amount of direction provided by the inventor and the existence of working examples: Applicants have provided no specific examples whatsoever of carrying out the claimed method steps. It is unclear whether the claimed method was even employed in the Examples listed in the specification as none of the

modeling, determining of functions (either experimental or “expected”) or “characteristics of a spatial brightness function” are particularly set forth. The method steps are set forth in generic language in the claims and no details on how they are to be carried out are set forth in the instant specification.

(8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure: The instant specification does not provide to one skilled in the art a reasonable amount of guidance with respect to the direction in which the experimentation should proceed in making and using claimed method. Note that there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and use the invention as broadly as it is claimed. *In re Vaeck*, 947 F.2d 488, 496 & n.23, 20 USPQ2d 1438, 1445 & n.23 (Fed. Cir. 1991). Therefore, it is deemed that further research of an unpredictable nature would be necessary to make or use the invention as claimed.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 29-44, 49-57, 60-64 and 66-73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. There is confusion as to whether “particles” or “molecules” are characterized in the claimed method. See claim 29 and dependent claim 40. A molecule is

not a particle. While applicant may be his or her own lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term. See *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947).

- B. Claim 31 recites that “characteristics of the spatial brightness function are values of volumes of sections of the measurement volume corresponding to a selected set of values of the spatial brightness”. It is simply unclear what is meant by this terminology. Moreover, how is the “selected set” to be selected?
- C. Claim 32 recites that “the volumes are considered as variables depending on modeling parameters of the spatial brightness function”. It is simply unclear what is meant by this terminology. What are the “modeling parameters”?
- D. Claim 32 recites that “pinhole dimensions and convergence angle of an incident laser beam are modeling parameters”. This is also confusing. There is insufficient antecedent basis for “incident laser beam” (also, incident to what?).
- E. Claim 34 is confusing because it is unclear how the “determination of the values of the parameters which yield the closest fit” to be determined.
- F. There is insufficient antecedent basis for “sample volume” in claim 50.
- G. There is insufficient antecedent basis for “equipment” in claim 67.
- H. Claim 71 recites the term “few”. This is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of

ordinary skill in the art would not be reasonably apprised of the scope of the invention.

***Status of Claims/Conclusion***

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie Garcia Baker, Ph.D. whose telephone number is (703) 308-0065. The examiner is on an increased flextime schedule but can normally be reached on Monday-Thursday and alternate Fridays from 9:30 to 7:00.

12. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang, can be reached at (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie Garcia Baker, Ph.D.  
March 21, 2003



MAURIE GARCIA BAKER PH.D.  
PRIMARY EXAMINER